NOV 17 2005

K043367

510(K) SUMMARY

Date: 19 June 2003

Submission Correspondent: Emergo Group, Inc.

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Contact: Mr. Rene van de Zande

Submission Sponsor: LACE Elettronica s.r.l.

Trade Name: **GLAID Ocular Electrophysiology Device**
Common Name: Photostimulator
Classification: Ophthalmology

Description: The GLAID Ocular Electrophysiology Device generates a display of photic stimuli which the patient observes as a pattern of alternating dark and white bars or checks. The electrical response of the patients' eye is monitored and recorded. The patients' response is measured using electrodes placed on the patients' face and eye

Intended Use: The GLAID device is indicated for use in the measurement of visual electrophysiologic potentials, including the electroretinogram (ERG), pattern electroretinogram (PERG), visual evoked potential (VEP) and electrooculogram (EOG), as an aid in the diagnosis and management of Glaucoma when used in conjunction with other established methods of diagnosis and disease management.

Predicate Devices: The predicate devices referenced in this submission are: the Electro-Diagnostic Imaging, Inc. VERIS System, the Doran Instruments Inc. Maculoscope, and the LKC Technologies Inc. Electroretinograph.

Summary and Conclusions Regarding Substantial Equivalence:
By definition, a device is substantially equivalent when the device has the same intended use and the same technological characteristics as the predicate device, or has the same intended use and different technological characteristics, but it can be demonstrated that the device is as safe and effective as the predicate device and the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device.

The differences between the GLAID Ocular Electrophysiology Device and the predicate devices cited do not raise any different questions regarding safety and effectiveness. The differences in the technological characteristics are minimal, and the associated procedures are nearly identical. The Intended use is identical to the intended use of the previously cleared predicate devices, and the indications are equivalent.

The device, as designed, is as safe and effective as the predicate devices, and the device is substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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LACE Elettronica s.r.l.
c/o Ian P. Gordon
Emergo Group, Incorporated
2519 McMullen Booth Road
Suite 510-295
Clearwater, FL 33761

Re: K043367
Trade/Device Name: GLAID Ocular Electrophysiology Device
Regulation Number: 21 CFR 882.1890
Regulation Name: Evoked Response Photic Stimulator
Regulatory Class: Class II
Product Code: GWE
Dated: October 19, 2005
Received: October 24, 2005

Dear Mr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 043367

Device Name: GLAID Ocular Electrophysiology Device

Indications for Use:

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(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K043367

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)